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Comparison f the effect of botulinum toxin A (Botox (R)) with the highly-purified neurotoxin (NT 201) in the extensor digit rum brevis muscle test

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Objective:

The extensor digitorum brevis muscle test is used to assess the effect of different doses of botulinum toxin (BoNT) in patients with BoNT-antibodies. In the present study, we compared the marketed toxin BOTOX (R) (Allergan, USA), a biotechnically synthesized botulinum toxin type A which contains the neurotoxin, hemagglutinins, and a nontoxic bacterial protein with NT 201 (BioteCon GmbH, Germany), a highly purified new product which consists of the pure Neurotoxin.

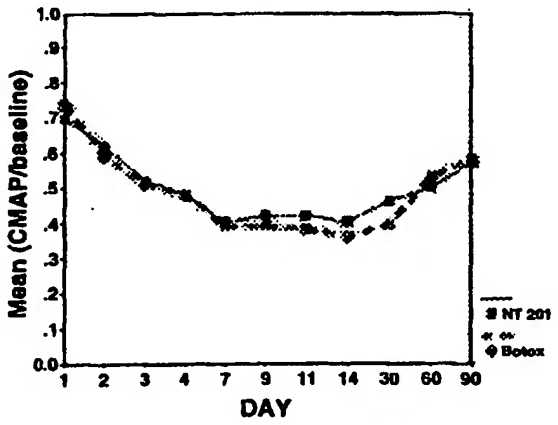
Methods:

In an intra-individual controlled trial, n = 14 healthy male volunteers (aged from 26.5 to 45.8 years with a mean of 32.1 years) were studied. For each subject, 4 MU BOTOX (R) were injected in a blinded manner in the EDB muscle of one leg and 4 MU NT 201 in the contralateral EDB. The compound muscle action potential (CMAP) was measured by surface EMG electrodes before and after injection. These CMAP measurements after injection were done at day 1, 2, 3, 4, 7, 9, 11, 14, 30, 60, 90.

The effect on the CMAP, its onset and duration, was calculated as percent decline in CMAP post injection (% paralysis).

Results:

On day 1, 80% of the EDB muscles injected with NT 201 showed a 20% CMAP decline compared to baseline, and only 65% of the EDB muscles injected with BOTOX (R) showed 20% CMAP decline. Both drugs produced a maximum decline between day 7 and day 14 (at around 40% of the baseline). At day 90, administration of both drugs resulted in approximately 60% of CMAP decline compared to baseline (see figure below).



Both drugs were well tolerated.

Conclusion:

The onset of the paralytic effect appears to be faster with NT 201 based on 20% CMAP decline. The maximum effect on CMAP and duration of both drugs were comparable. Based on the CMAP endpoint in this human pharmacology trial, NT 201 seems to be as effective as BOTOX (R).

Course of the mean percent baseline CMAP level (EMG)